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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/401,636	09/22/1999	LARS T. HELLMAN	10223/006001	4922

7590

01/30/2002

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EXAMINER

JAMROZ, MARGARET E

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 01/30/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/401,636

Applicant(s)

HELLMAN, LARS T.

Examiner

Margaret E Jamroz

Art Unit

1644

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 January 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☒ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.Claim(s) objected to: none.Claim(s) rejected: 1,2,4-11 and 25-54.Claim(s) withdrawn from consideration: none.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

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### DETAILED ADVISORY ACTION

1. The proposed amendment filed 1/23/02 raises potential issues of new matter and new issues that would require further consideration and/or search.

The proposed amendment to claim 33, line 4, to include positions 117-178 of Figure 2A raises potential issues of new matter.

Positions 117-178 of figure 2A comprises several different sequences from different species (rat vs mouse CH3) which would also require further consideration and/or search.

The recitation of Figure 2A in claim 33, line 5 raises potential issues with respect to 35 USC 112 because it does not recite a SEQ ID NO in the Brief Description of the Drawings.

2. Claims 1-2, 4-11, and 25-54 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "an immunogenic polypeptide comprising a nonself IgE CH2 domain, a self IgE CH3 domain, and a nonself IgE CH4 domain" (claim 1), does not reasonably provide enablement for

(A) "An immunogenic polypeptide comprising a self IgE portion and a nonself IgE portion, and wherein said self IgE portion comprises at least a portion of a CH3 domain of IgE" (claim 1),

(B) "An immunogenic polypeptide of claim 1 wherein the nonself portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said nonself IgE portion" (claim 5),

(C) "The immunogenic polypeptide of claim 5, wherein said first region comprises at least a portion of an IgE CH2 domain" (claim 6), or

(D) "The immunogenic polypeptide of claim 5, wherein said first region comprises at least a portion of an IgE CH4 domain" (claim 7),

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the same reasons in Paper Nos 18, 9, 13, and 16, mailed 12/4/2001, 07/03/00, 01/02/01, and 06/28/01, respectively.

Applicant's arguments filed 1/24/2002 have been fully considered but they are not persuasive.

Applicant argues that one of skill in the art would know how to make a "portion" of a polypeptide. Applicant did not respond to the enablement rejection of claims 6-7 regarding "region".

It is the examiner's position that a "region" or a "portion" of a CH domain could constitute as little as a single amino acid which would not be sufficient to generate an antibody response against the self IgE "region" or "portion" when said self IgE "region" or "portion" is surrounded by a single amino acid of a non-self IgE "region" or "portion" on either side.

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3. Claims 1-2, 4-11, and 33-40 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons set forth in Paper Nos 18 and 16, mailed 12/4/2001 and 6/28/2001, respectively. This is a New Matter rejection.

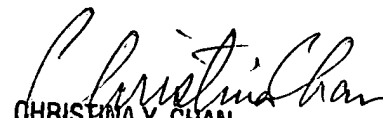
It is applicant's position is that the specification discloses immunogenic polypeptides having an N-terminal portion, thus applicant was in possession of immunogenic polypeptides comprising a non-self IgE portion that consists essentially of an N-terminal portion. Applicant amended the claims to recite "comprising", and further argues that original claims 6 and 7 recite an immunogenic polypeptide having a non-self IgE *portion* that *comprises at least a portion of* a CH2 domain or a CH4 domain, respectively.

It is the examiner's position that the recitation of "a non-self IgE *portion* that *comprises at least a portion of*" does not meet the open-ended language of "comprising" because at least a portion of could be as little as a single amino acid, and "comprising" is open-ended language that includes amino acid sequences outside of the fragment (e.g. CH domain) disclosed. It is the examiner's position, therefore, that *consisting essentially of* in claims 6 and 7, therefore, constitutes new matter.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz whose telephone number is (703) 308-8365. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Margaret (Megan) Jamroz, Ph.D.  
Patent Examiner  
Technology Center 1600  
January 29, 2002

  
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